CASE STUDY

EMERALD CLINICAL TRIALS

Emerald Clinical Guides Sponsor with Limited Clinical Trial Experience in Phase II Melanoma-TIL Trial

Proactive identification of issues potentially affecting trial outcome led Emerald Clinical to step in and provide services above and beyond original statement of work with full services, from protocol amendment to expanding manufacturing capabilities and easing patient waiting times.

SITUATION

Emerald Clinical was contracted by a small biotechnology company for a Phase II, multi-center, single-arm study to assess the safety and efficacy of cell transfer therapy using autologous tumor infiltrating lymphocytes (TIL) followed by IL-2 treatment of patients with metastatic melanoma.

As Emerald Clinical has conducted over 300 oncology studies, we were a good fit for a small company with limited clinical trial proficiency and in the process of rapid expansion of their clinical trial team. Our extensive experience includes all phases of oncology programs including, Maximum Tolerated Dose (MTD), Phase I, II and III and late-phase trials, health economics and outcomes research. Our full services team is comprised of scientific leaders, doctors, nurses, biostatisticians and trial management professionals who work together to ensure timely delivery of quality trial data. Our scientific leadership model is recognized internationally as being highly effective in helping sponsors implement the most effective trials possible with innovative solutions that produce quality outcomes within tight timelines and limited budgets.

CHALLENGES

Clinical trials involving live tissue as well as patient harvest and infusion involve many logistical issues. At the outset of this trial there was a delay in the initial TIL manufacture by the sponsor-contracted vendor. In addition, the initial protocol included a variable and extensive waiting period between tumor harvest and TIL infusion requiring patients to be in a "washout" for extended periods of time. All aspects of the trial/patient process needed fine tuning, including increasing lab capacity, coordinating tumor harvesting procedure and infusion schedules with variable product expansion timelines at TIL facilities, and aligning shipment of TIL product to be received at site and stored

Teamwork and full-service expertise get Phase II trial back on track

Protocol amendment mitigating risks associated with patient deterioration

Shipping coordination, oversight and risk mitigation for live tissue exchange including communications, scheduling, transportation and 24/7 back-up availability

Improvement of tissue processing, handling and quality control increasing affirmation of quality and viability of final TILs for infusion

Assessment and coordination of expanded facilities cutting TIL process timelines in half

or infused same day to patient. As the trial evolved, there was also a cryo-preserved TIL product which required proper receipt and storage by sites.

"Emerald Clinical has a track record of creating individual solutions for all types of trials and has the expertise, personnel and flexibility to quickly mitigate risks and restore order in situations where CRO transition has become essential. We have the resources to help get a trial back on track both rapidly and efficiently," stated **Maria Ali, Chief Medical Officer, Emerald Clinical.**

SOLUTIONS

Early on in the process Emerald Clinical developed the lab manual, site documents and site workflows to address manufacturing delays. Amendment for palliative radiation and addition of a cryo-preserved option helped alleviate patient waiting period between tumor harvest and TIL.

To coordinate tumor harvest and shipping, Emerald Clinical developed an on-call/notification system between couriers and the project team. We also coordinated live tissue shipments and receipts, and our team was available 24/7 to address transit issues.

Our team also added TIL facilities and developed a scheduling system with slot reservations for tissue harvest to mitigate the issue of limited lab capacity. An authorization process was created for lymphodepletion that coordinated infusion schedules and manufacturing timelines.

Since sponsor team resources were limited at project start and slowly underwent significant growth, Emerald Clinical took on the role of on-boarding the new sponsor team members (including their project manager) on the protocol and processes that were set-up since the study started and also provided additional staff to support the project. As the project progressed, the sponsor agreed to add more sites to be managed by our team from site identification through site initiation and enrollment.

RESULTS

- Costly delays, complications and difficulties were avoided and study enrollment was improved.
- Logistics ran smoothly, quality and efficacy of critical tissue was preserved.
- Enrollment targets were met and treatment time was reduced.
- Manufacturing capabilities were expanded including a cryopreserve lab.
- Patient experience was enhanced.

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